

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

ASTELLAS INSTITUTE FOR REGENERATIVE MEDICINE, and STEM CELL & REGENERATIVE MEDICINE INTERNATIONAL, INC.,))
Plaintiffs,)	C.A. NO. 1:17-cv-12239-DJC
v.)	ORAL ARGUMENT REQUESTED
IMSTEM BIOTECHNOLOGY, INC., XIAOFANG WANG, and REN-HE XU,)	FILED UNDER SEAL
Defendants.)	LEAVE TO FILE GRANTED ON 3/16/20 (Dkt. 168)

**MEMORANDUM OF LAW IN SUPPORT OF
DEFENDANTS' MOTION *IN LIMINE*
TO PRECLUDE IMPROPER EXPERT TESTIMONY
REGARDING STATE LAW CLAIMS**

INTRODUCTION

Pursuant to the Court’s Amended Scheduling and Pretrial Order dated September 26, 2019 (Dkt. 106), Fed.R.Civ.P. 7, and L.R. 7.1, Defendants Imstem Biotechnology, Inc. (“Imstem”), Xiaofang Wang (“Wang”), and Ren-He Xu (“Xu”) (collectively “Defendants”) seek *in limine* relief limiting Plaintiffs Astellas Institute for Regenerative Medicine (“Astellas”) and Stem Cell & Regenerative Medicine International, Inc.’s (“SCRMI”) (collectively “Plaintiffs”) designated expert Dr. Lisa Fortier (“Dr. Fortier”) from testifying regarding Plaintiffs’ state law causes of actions. Dr. Fortier’s opinions beyond inventive contribution¹ invade the province of the Court and jury, are not helpful to the jury and are outside of her expertise.²

GENERAL FACTUAL BACKGROUND³

This inventorship dispute arises from the parties’ once-amicable scientific collaboration developing protocols for making, and methods of using, mesenchymal stem cells (“MSCs”). First. Am. Compl. (Dkt. 113) ¶ 9. MSC’s are quasi-differentiated cells that have the ability to become a wide range of bodily cells, such as bone, fat, and cartilage. While less pluripotent than human embryonic stem cells (“hESC”), they retain the ability to change and develop into a wide range of cell types. Prior to 2010, scientists had developed a range of ways to make a variety of

¹ The proper nature and scope of Dr. Fortier’s testimony regarding “inventive contributions” is explained in Defendants’ Motion and Memorandum of Law to Preclude Improper Testimony Regarding Collaboration and Inventorship, filed concurrently herewith. That motion explains, in greater detail, the contours of what Dr. Fortier should – and should not – be allowed to testify to with respect to (i) underlying facts versus (ii) scientific evaluations of comparative “inventive contribution.”

² The instant motion is equally applicable to Astellas’s other expert, Dr. Brivanlou. His report does not appear to contain any formal opinions concerning the state-law claims and the risk of his testifying regarding those underlying facts or the claims themselves seems more remote. Defendants would, of course, expect the ruling on the instant motion to govern his testimony as well.

³ Given the Court’s familiarity with this case, Defendants offer this limited contextual background for purposes of the instant Motion, as well as other co-pending Motions *in Limine*.

types of MSCs.⁴

Plaintiffs allege that in 2009 two of their scientists (Kimbrel and Lanza) developed what is essentially a recipe for making a new kind of MSC derived from hemangioblasts (“hemangioblast-derived MSCs” or “HB-MSCs”). The recipe was based, in large part, on a protocol previously developed and published by her colleague Dr. Shi-Jiang Lu.

In July 2010, Drs. Lu, Xu, and Wang met to discuss a potential collaboration, during which Drs. Xu and Wang proposed that they test the effectiveness of MSCs to treat autoimmune disease – Dr. Wang’s area of expertise. Am. Countercl. (Dkt. 20) ¶¶ 18-20.⁵ Drs. Wang and Xu specifically proposed treatment of multiple sclerosis. *Id.* In a subsequent email Dr. Wang again suggested testing the effectiveness of MSCs to treat autoimmune disease.

Defendants’ experiments started yielding results in the early winter of 2010. *See id.* ¶ 24. While the collaboration was ongoing, Drs. Wang and Xu began making substantial modifications to the HB-MSC protocol – including changing the first step, adding glycogen synthase kinase-3 inhibitor, irradiating the resulting cells, and chemically “characterizing” the cells.

On November 30, 2011, without informing Drs. Wang or Xu, Dr. Kimbrel (and other of Plaintiffs’ employees) filed provisional patent Application No. 61/656,358. Dr. Kimbrel did not list Drs. Wang, Xu, or Lu as inventors. *Id.* ¶¶ 26, 35.

During prosecution, the provisional application was subjected to a “restriction requirement” by the U.S. Patent & Trademark Office (the “PTO”), which divided the claims into two groups: (i) claims concerning the recipe for *making* the HB-MSC’s; and (ii) claims directed to methods of *using* any such cells to treat *inter alia* autoimmune diseases. The former

⁴ MSCs until that time had been derived from bone marrow, adipose tissues, umbilical cord blood, or directly from hESCs.

⁵ At the time, the Plaintiffs employed Dr. Lu.

ultimately issued as the ‘321 patent. The latter ultimately issued as the ‘956 patent.⁶ See generally Answer Ex. A (Dkt. 20-1) (‘956 Patent) at 1.

In parallel, Drs. Xu and Wang filed a patent application on their new version of the HB-MSC protocol. It issued as U.S. Patent No. 9,745,551 (the “‘551 Patent”).⁷

On November 13, 2017, Plaintiffs filed the instant action, alleging two counts of Correction of Inventorship for the ‘551 Patent (one alleging that Drs. Kimbrel and Lanza were the sole inventors and one alleging that they are joint inventors with the current inventors), Conversion, Unjust Enrichment, Unfair Trade Practices (93A), Misappropriation of Trade Secrets, and Negligent Misrepresentation. By Order dated October 2, 2019, Plaintiffs were permitted to amend the complaint, which they did on October 3, 2019 to add a count for breach of contract.

POTENTIAL EVIDENCE AT ISSUE

On October 4, 2019, Plaintiffs served the Opening Expert Report of Lisa Fortier, DVM, PH.D., purporting to address a number of topics, including Inventorship, Requirements for Invention, Unfair Trade Practices, Conversion, Unjust Enrichment, Misappropriation of Trade Secrets, Negligent Misrepresentation, and Breach of Contract. Ex. 1⁸ (Dr. Fortier’s Opening

⁶ More precisely, the Plaintiffs filed a continuation-in-part application claiming priority to the ‘358 application (No. 13/691,349). During prosecution of *that* application, the PTO issued the restriction requirement. The Plaintiffs elected to drop the “use” claims from that application and pursue them instead in a new application (No. 13/905,526). The former (No. 13/691,349) became the ‘321 Patent. The latter (No. 13/905,526) became the ‘956 Patent.

⁷ In its Memorandum and Order on Cross Motions for Summary Judgment, the Court found that Drs. Kimbrel and Lanza should be added as co-inventors on the ‘551 Patent. Memorandum and Order on Cross Motions for Summary Judgment dated March 4, 2020 (“Order”) at page 9 (Burroughs, J.). The only disputed issue with respect to the ‘551 patent is whether Defendants’ contributions are “not insignificant,” such that they can remain as named inventors on that patent.

⁸ All exhibits are attached to the Declaration of Timothy R. Shannon in Support of Defendants’ Motions *in Limine* (“Shannon Decl.”), filed contemporaneously.

Report dated October 4, 2019) (hereinafter “Fortier Report”) at pp. 6-13.⁹ In her Report, after enunciating her “understanding” of the legal elements for each state law cause of action, Dr. Fortier renders her “opinion” that the Defendants are liable for each state-law cause of action. *Id.* pp. 83-94.

Defendants object to Dr. Fortier’s (1) parroting or validating the fact testimony of the actual fact witnesses and her characterization of the historical events leading up to the suit;¹⁰ and (2) offering any opinions or testimony (foreshadowed in her expert report) to the effect that “Defendants are liable” for the state law claims. *See* Fortier Report at page 5, ¶ 18; pp. 83, ¶ 183; 84, ¶ 187; 87, ¶ 193; 89, ¶ 200; 91, ¶ 206; and 92, ¶ 211.¹¹

ARGUMENT

I. Dr. Fortier’s Testimony and Opinions Regarding State Law Causes of Action are Inadmissible.

A. Dr. Fortier is Unqualified to Offer Expert Legal Opinions.

A witness rendering an expert opinion must be “qualified by knowledge, skill, experience, training, or education....” Fed. R. Evid. 702.

Dr. Fortier is not qualified to opine on the state law claims. She is not a lawyer and does not have any legal education, experience, or training. *See* Memorandum and Order on Cross Motions for Summary Judgment dated March 4, 2020 (at page 19) (Burroughs, J.) (hereinafter March 4, 2020 Order); *see also* Ex. 3 (Deposition of Lisa Fortier, taken December 4, 2019

⁹ The opinions regarding unfair trade practices, conversion, unjust enrichment, misappropriation of trade secrets, negligent misrepresentation, and breach of contract are collectively referred to herein as the “state law causes of action” or “state law claims.”

¹⁰ *See* note 1, *supra*.

¹¹ As discussed in Defendants’ Motion *in Limine* to Preclude Improper Testimony Regarding Collaboration and Inventorship, Defendants do not seek to preclude Dr. Fortier from opinions that focus on whether any person’s contribution to one of the subject patents was or was not insubstantial contribution (*i.e.*, “inventive contribution”). *See* note 1, *supra*. Defendants do not, however, concede that Dr. Fortier may offer testimony regarding the factual events as to who-invented-what or other facts that are necessary predicates to the inventorship question. *See id.*

(hereinafter “Fortier Deposition”) at 188:9-10, 23-25; 193:11, 14-15; 194:15; 195:14-16; 195:25-196:5; 199:16-21; 204:6-8, 23-25; 206:24-26; Fortier Report, pp. 1-4, ¶¶ 2-11. Rather, Dr. Fortier’s background, education, and experience is in veterinary medicine. Fortier Report at pp. 1-2, ¶¶ 3-5.

Notably, this Court recently determined that Dr. Fortier is not qualified to offer a legal opinion. March 4, 2020 Order at p. 19. In its Order denying Plaintiffs’ motion for partial summary judgment, this Court held that “Dr. Fortier is not an attorney and was not qualified to provide a legal opinion regarding the existence of a contract or its breach.” *Id.*

Just as Dr. Fortier was unqualified to provide a legal opinion regarding a contract, she is unqualified to render any legal opinion regarding the other state-law claims: [REDACTED]

[REDACTED]
[REDACTED]

[REDACTED]¹² As she is unqualified to offer opinions on the state law causes of action, Dr. Fortier’s testimony must be limited to her opinions regarding inventive contribution.¹³

B. Dr. Fortier’s State Law Opinions Improperly Invade the Province of the Judge and Jury.

1. Standard

Even if Dr. Fortier were qualified to discuss the state law claims (she is not), her opinions regarding Plaintiffs’ state law claims are inadmissible because they are not the proper

¹² [REDACTED]

[REDACTED] See, e.g., Fortier Deposition at 187:24-198:17; 190:10-17; 194:24-

195:16.

[REDACTED] Fortier Deposition at 189:2-5; 203:24-204:4.

¹³ Because Dr. Fortier is not an expert with respect to the state law claims, she cannot rely on Federal Rule of Evidence 703, which allows experts to rely on inadmissible evidence. Thus, her testimony as to any facts or circumstances related to the state law claims amounts to inadmissible hearsay and is inadmissible on that basis in addition to those cited herein.

subject of expert testimony. Testimony regarding questions of law or the elements of a legal claim are not helpful to the jury's understanding the evidence or determining a fact in issue.

Nieves-Villanueva v. Soto-Rivera, 133 F.3d 92, 100 (1st Cir. 1997). Such testimony is not helpful because the judge, not the expert, educates the jury on the applicable principles of law. *Id.* 133 F.3d at 99 (citations omitted). Moreover, allowing an expert to testify to legal conclusions, which are the sole domain of the judge, is “at best cumulative and at worst prejudicial.” *Id.*

Facts masquerading as expert opinion are also unhelpful and, as such, inadmissible. *See U.S. ex rel. Dyer v. Raytheon Co.*, 2013 WL 5348571, * 12 (D.Mass. September 23, 2013) (Woodlock, J) (citations omitted) (an expert merely bolstering “the credibility of [a party’s] fact witnesses by mirroring their version of events” is improper). According to the First Circuit, “[e]xpert testimony does not assist where the [trier of fact] has no need for an opinion because it can be easily derived from common sense, common experience, the [trier of fact’s] own perceptions, or simple logic.” *U.S. v. Zajanckauskas*, 441 F.3d 32, 39 (1st Cir. 2006) (quoting 29 Charles Alan Wright & Victor James Gold, *Federal Practice and Procedure* § 6264 (2005)).

While an expert is given significant leeway for opinions within her area of expertise, “an expert is not given ‘carte blanche’ to substitute [her] own views on matters for the jury.” *Perez-Garcia v. Puerto Rico Ports Authority*, 873 F. Supp. 2d 435, 441 (D.P.R. 2012) (citing *Dinco v. Dylex, Ltd.*, 111 F.3d 964, 973 (1st Cir. 1997)). As a result, despite Fed. R. Evid. 704’s abolition of the ultimate issue rule, “opinions that merely tell the jury what result to reach should be deemed inadmissible under Rules 701, 702 and 403.” *Perez-Garcia*, 873 F. Supp. 2d at 441-442. Given the foregoing, “[a] district court has broad discretion to exclude expert

opinion evidence about the law that would impinge on the roles of the judge and the jury.”

Pelletier v. Maine Street Textiles, LP, 470 F.3d 48, 54-55 (1st Cir. 2006)(citations omitted).

Despite Dr. Fortier’s claim that [REDACTED]

[REDACTED] Fortier Report at p. 83, ¶ 183; p. 84, ¶ 187; p. 87, ¶ 193; p. 89, ¶ 200; p. 91, ¶ 206; and, p. 92, ¶ 211. Enunciating the elements of the state law claims is the sole responsibility of this Court; Dr. Fortier’s attempt to do so is of no help to the jury. *See Contour Design, Inc. v. Chance Mold Steel Co.*, 794 F. Supp. 2d 315, 320 (D.N.H. 2011) (expert opinions regarding the reach of the Uniform Trade Secrets Act, how courts otherwise define trade secrets, and the scope of contractual terms are improper). As the Court has the sole authority to inform the jury of the elements of the state law causes of action, Dr. Fortier should be precluded from rendering any opinions as to the elements of the causes of action.¹⁴

Dr. Fortier’s opinions on the state law causes of action similarly invade the jury’s role. Inexplicably, Dr. Fortier’s opinions specifically – and improperly – tell the jury what decision it should reach. Dr. Fortier’s “opinions” include [REDACTED]

[REDACTED] These are not expert

¹⁴ Dr. Fortier’s opinions on the state law causes of action each flow from her articulation of the legal standard for each claim, following which she purports to apply the standard to her view of the facts. Without the legal predicate, her opinions are truly nothing more than her reiteration of the facts and her verdict, neither of which are the proper subject of expert testimony.

opinions; they are verdicts that inappropriately supplant the jury's role at trial. *See, e.g.*, *Contour Design, Inc.*, 794 F. Supp. 2d at 321 (experts cannot substitute their views for matters "well within the ken of the jury").

In short, Dr. Fortier's opinions on Plaintiff's state law claims are categorically unhelpful to the jury. First and foremost, she is unqualified to offer these opinions. Even if she were qualified, her statement of the legal standards for the state law claims usurps the Court's role, her view of the facts improperly bolsters the credibility of Plaintiffs' witnesses, and her opinions that the Defendants are liable for the state law claims impinges on the jury's role. The experts should be limited to their proper role in an inventorship dispute: describing scientific principles and weighing the comparative importance/significance of various elements of the claims of the patents-in-suit. They should not testify on the separate, antecedent, factual question of who actually contributed the idea during the collaboration. *See note, 1 supra.*

II. Dr. Fortier Cannot Vouch for the Plaintiff's Witnesses' Veracity

In addition to many of the views Dr. Fortier enunciated in her report are improper attempts to buttress Plaintiffs' credibility and inflame the passions of the jury, not expert opinion. *See U.S. v. Shay*, 57 F.3d 126, 131 (1st Cir. 1995) ("an expert's opinion that another witness is lying or telling the truth is ordinarily inadmissible pursuant to Rule 702 because the opinion exceeds the scope of the expert's specialized knowledge and therefore merely informs the jury that it should reach a particular conclusion"). For example, she relies on Dr. Kimbrel's testimony and Plaintiffs' exhibits to opine that [REDACTED]

[REDACTED] *Id.* pp. 89-90, ¶¶ 201, 202. This is akin to Dr. Fortier testifying that Dr. Kimbrel is more credible than are other witnesses.

Dr. Fortier also improperly offers her moral judgment concerning events that occurred outside of her presence, and contents of emails to which she was not a party. For example, according to Dr. Fortier, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] These and similar statements are not expert opinions or analysis. They are Dr. Fortier vouching for the veracity of the Plaintiffs' witnesses and evidence, and the morality of Defendants' actions. There is simply no basis for Dr. Fortier to offer her personal moral judgments of the conduct of a party. These characterizations of evidence under the guise of expert testimony are an improper attempt to bolster the Plaintiffs' case and will not help the jury "to understand the evidence or to determine a fact in issue...."

Fed. R. Evid. 702(a)

III. The probative value of Dr. Fortier's opinions on Plaintiffs' state law claims, if any, is substantially outweighed by the unfair prejudice and confusion they will cause.

A. Standard

Pursuant to Fed. R. Evid. 403:

The court may exclude relevant evidence if its probative value is substantially outweighed by a danger of one or more of the following: unfair

15 [REDACTED]

[REDACTED] *See, In re Loestrin 24 Fe Antitrust Litigation, __ F. Supp. 3d __, 2019 WL 7286764, * 9 (D.R.I. December 12, 2019 (Smith, J.) (excluding expert testimony on intent and state of mind of mind and speculation about the patent examiner's state of mind); see also, Dyer, 2013 WL 5348571, *13 ("it is well settled that an expert cannot bring any scientific, technical, or specialized knowledge to bear on another person's knowledge.... [The expert] cannot testify or opine on the issue of [the defendant's] knowledge or intent").*

prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence.

Expert testimony is subject to Fed. R. Evid. 403, and is properly excluded “if its probative value is substantially outweighed by the risk of unfair prejudice it creates.” *U.S. v. Montas*, 41 F.3d 775, 783 (1st Cir. 1994)(citations omitted).

Indeed, such evidence presents a special level of complexity in constructing the balance between probative value and unfairly prejudicial effect. This complexity arises out of the concern that, because of an expert’s stature *qua* expert, jurors may assign more weight to expert testimony than it deserves. Because such testimony can carry with it an unwarranted aura of special reliability and trustworthiness, courts must guard against letting it intrude in areas that jurors, by dint of common experience, are uniquely competent to judge without the aid of experts. This concern, where pertinent, should legitimately factor into a trial court’s Rule 403 analysis.

U.S. v. Pires, 642 F.3d 1, 12 (1st Cir. 2011)(italics in original)(internal quotations and citations omitted).

B. Discussion

Dr. Fortier’s opinions on the state law claims have little, if any, probative value. She is not qualified to render the opinions. Her views of the legal constructs are inadmissible because they invade this Court’s role. Her views of the facts are nothing more than an improper and inadmissible attempt to vouch for and reinforce the Plaintiffs’ testimony and evidence. Dr. Fortier’s verdicts are clearly an invasion of the province of the jury. As her view of the law, the facts, and her verdicts are unhelpful to the jury, her testimony on the state law claims has no probative value.

Assuming, *arguendo*, that this Court determines that Dr. Fortier’s views regarding the state law claims have probative value, that value is far outweighed by the unfair prejudice they will cause. Dr. Fortier has a lengthy CV that will likely impress any jury. She has had what appears to be a distinguished career as a veterinarian. As a result, the jury will likely give Dr.

Fortier's testimony greater reliability and credibility than is warranted. The undue weight that the jury will give to Dr. Fortier on her views of the facts and law for the state law issues is unfairly prejudicial, particularly because Dr. Fortier has no legal education or experience. Under the circumstances, the unfair prejudice that would result from Dr. Fortier expounding on these legal issues far outweighs its probative value which is, if anything, negligible.

In addition, Dr. Fortier bases her opinions that Defendants actions were unfair, unethical, or unscrupulous are moral judgments, not legal determinations. Allowing an expert to vouchsafe for the Plaintiffs' witnesses' veracity while also placing a moralistic spin on those facts is unfairly prejudicial and far outweighs the probative value of Dr. Fortier's state law views.

In the end, Dr. Fortier's state law opinions do nothing more than place her imprimatur on Plaintiffs' claims and, as such, are properly excluded under Rule 403. *See Tuli v. Brigham & Women's Hosp., Inc.*, 892 F.Supp. 2d 208, 212 (D.Mass. 2009) (Where an expert's opinion "is doing little more than putting [her] imprimatur on [a party's case]," it is properly excluded under the balancing requirements of Fed. R. Evid. 403).

CONCLUSION

For the reasons set forth herein, Defendants respectfully ask that this Court grant Defendants' Motion *in Limine* to prevent Dr. Fortier's from testifying regarding Plaintiffs' state law causes of actions.

March 16, 2020

Respectfully submitted,

IMSTEM BIOTECHNOLOGY, INC., REN-HE XU and XIAOFANG WANG,

By their Attorneys,

/s/ Timothy R. Shannon

Timothy R. Shannon, MA Bar # 655325
Martha C. Gaythwaite, MA Bar # 187650
VERRILL DANA LLP
One Portland Square
Portland, Maine 04101
(207) 774-4000
tshannon@verrill-law.com
mgaythwaite@verrill-law.com

Benjamin M. Stern, MA Bar # 646778
VERRILL DANA LLP
One Federal Street, 20th Floor
Boston, Massachusetts 02110
(617) 309-2600
bstern@verrill-law.com

Attorneys for Defendants

CERTIFICATE OF COMPLIANCE WITH LOCAL RULE 7.1

I hereby certify that, on March 13, 2020, counsel for Defendants conferred by telephonically with Counsel for Plaintiffs in a good faith effort to narrow or resolve the issues raised in the instant motion. Plaintiffs indicated they would oppose the instant motion.

Dated: March 16, 2020

/s/ Timothy R. Shannon

Timothy R. Shannon

CERTIFICATE OF SERVICE

I hereby certify that on March 16, 2020, I caused a true copy of the foregoing document to be served upon counsel of record:

Charles H. Sanders (BBO#646740) (via email; Charles.Sanders@lw.com)
LATHAM & WATKINS LLP
John Hancock Tower, 27th Floor
200 Clarendon Street
Boston, MA 02116
Tel: (617) 948-6022

Michael A. Morin (via email; Michael.Morin@lw.com)
David P. Frazier (via email; David.Frazier@lw.com)
Rebecca L. Rabenstein (via email; Rebecca.Rabenstein@lw.com)
555 Eleventh Street, N.W., Ste. 1000
Washington, DC 20004
Tel: (202) 637-2200; Fax: (202) 637-2201

/s/ Timothy R. Shannon
Timothy R. Shannon